



UPDATE: Permits, Registrations and Imports

Michael J. Firko, Director

Permits, Registrations & Imports (PRI)

(Biological and Technical Services)

ASTA / APHIS Meeting

Washington, DC

21 April 2005

APHIS Plant Health Programs - Revised Headquarters Organizational Structure March 2005

PHP Management Team

Exec. Director, Plant Health Programs
Associate Exec. Director – Permanent
Associate Exec. Director – IS Rotational
Director, QPAS
Director, PIM
Director, PRI
Director, TPC
Director, RC
Director, VRS

APHIS Plant Health Programs Office of the Executive Director (301) 734-8261

Alan Green, Executive Director
Jane Levy, Associate Executive Director
Mark Knez, IS Rotational Position

Policy, Planning, & Critical Issues

Eric Rudyj, Team Leader
(301) 734-7601
Strategic and Program Planning
Program Policy and Analysis

Program Data Management & Analysis

Alison Young, Program Data Manager
(301) 734-3821
Program Data Management
IT Applications and Customer Support

Quarantine Policy, Analysis, & Support

Bill Thomas, Director
(301) 734-8295
Cargo/Pax/Borders
Preclearance / Predeparture
SITC, Trade Compliance,
Surveillance Officers
Virtual Incident Command
System
AQIM
Quality Assurance
Data Management and
Analysis (DMA)
Database Management
ITDS, ATS
280/WADS QC
National Targeting Center
(N.T.C.)
Canine Policy
CBP Liaison

Phytosanitary Issues Management

Cathy Enright, Director
(301) 734-8262
Trade Directors
Assistant Trade
Directors
Commodity Specialists
Export Certification and
Accreditation
International Standards

Permits, Registrations & Imports

Mike Firko, Director
(301) 734-8758
Permit Services
Plants and Plant Products,
Pests, Soil Permits
Select Agent
Registrations
Pest Permit Evaluations
Microorganisms
Invertebrates
Select Agent
Registrations
Commodity Import
Analysis & Operations
Imports
Q-37
Risk Management

Taxonomy & Plant Clearance

Vacant, Director
(301) 734-5312
National Identification
Services
Coordination and Policy
National Identifiers
Pest Interception
Database Management
Plant Inspection Station
Policy and Support
CITES Policy & Support
Beltsville Inspection
Station Operations
Post Entry Quarantine
Plant Germplasm
Screening

Regulatory Coordination

Mike Lidsky, Director
(301) 734-8790
(Supervisor or Team Leader)
Development and Maintenance
of regulations
APHIS Library
Manuals Unit
Environmental Compliance
Coordination

Veterinary Regulatory Support

Maureen Bell, Director
(301) 734-7633
Animal Products and By-
Products
Foreign Garbage



PPQ Permit User Fees

- Working on draft regulations for Proposed Rule
- APHIS plans to publish Proposed Rule in 2005
- Includes all PPQ permit types



PPQ Permit User Fees

- Fees... ~\$100 - \$1,000
 - Fees based on “Activity Based Costing”
- Different fees for different types of permits, based on regulatory effort:
 - \$ - Plant & Plant Product
 - \$\$ - Timber & Timber Product
 - \$\$\$ - Departmental (Research) & Soil
 - \$\$\$\$ - Plant Pest & Noxious Weed



Steps We're Taking to Improve Efficiency and Response Time

ISO 9001

- Improvements result from:
 - Documentation/Redesign of Business Practices
 - Creating and Monitoring Performance Measures
 - Enhanced Communication, internal and external
- Currently certified: Plant & Plant Products
- Currently preparing documentation:
 - Plant Pest Permits
 - Soil Permits
 - Transit Permits

Average Permit Issuance Times

Type of Permit	No. days (2004)
Post Entry	2
Timber and Timber Products	2
Departmental	2
Soil	6
Canadian	6
Corn	2
Sugercane	1
Rice	1
Cotton	3
Brass	1
Transit	2



Steps We're Taking to Improve Efficiency and Response Time

ePermits

- Apply for, and issue permits electronically
- “Sign” permit conditions and State Review electronically
- Access through “eAuthentication”
- All PPQ Permits
- A single APHIS Permit Data Base (PPQ, VS, BRS)
 - other USDA Agencies ~ 2007?

Welcome to ePermits, your one stop Source for Agricultural Permitting

Username:

< PIS User >>

Password:

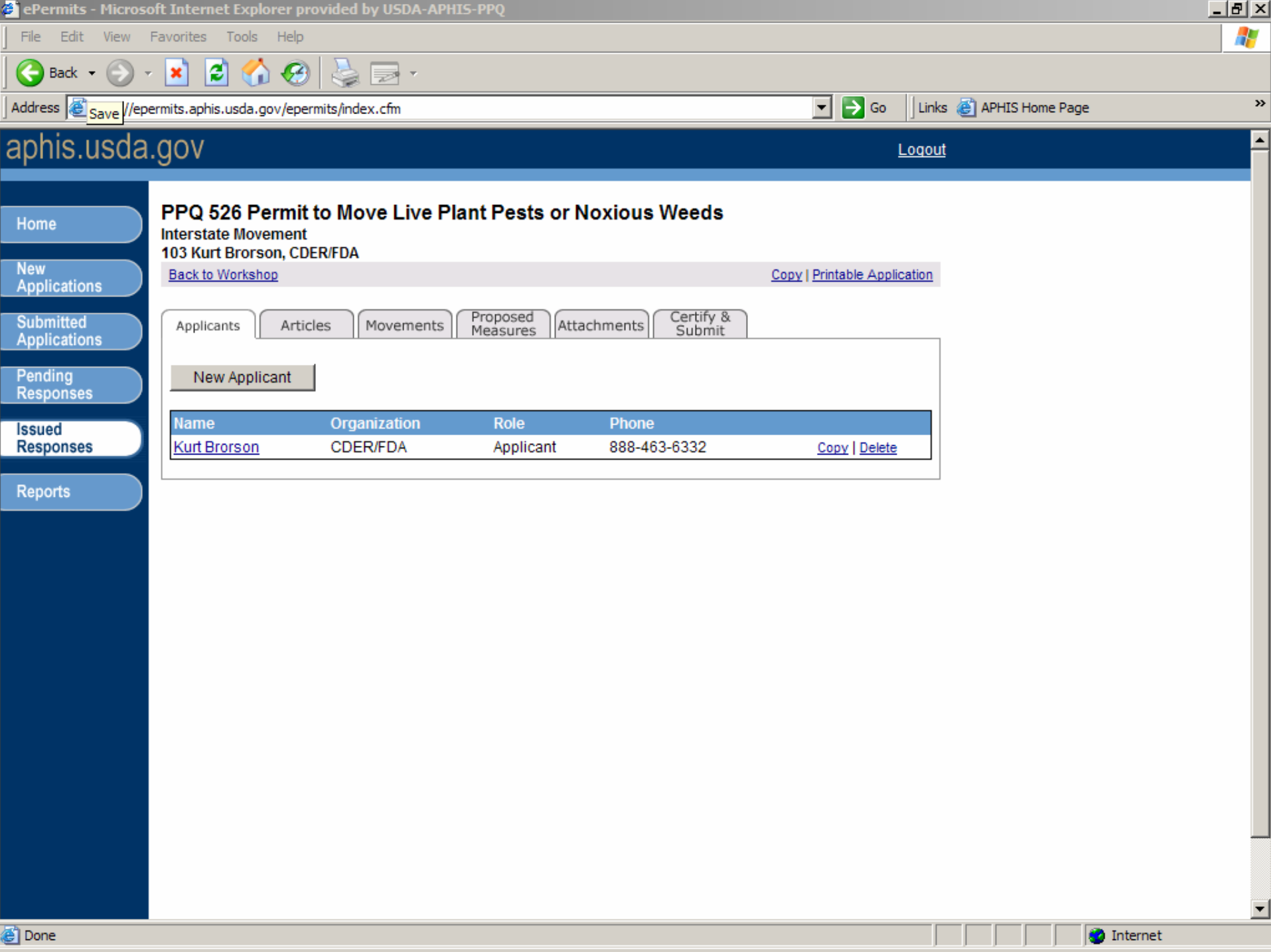
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Log In

New User? [Click here](#)

Log-in to start a fully enabled session.

You may explore portions of the site without log-in to determine if you are required to apply for a permit. Throughout ePermits, use the left side bar to navigate through functionalities. At any time, click on Home to return to this page.



- Home
- New Applications
- Submitted Applications
- Pending Responses
- Issued Responses
- Reports

PPQ 526 Permit to Move Live Plant Pests or Noxious Weeds

Interstate Movement
103 Kurt Brorson, CDER/FDA

[Back to Workshop](#) [Copy](#) | [Printable Application](#)

- Applicants
- Articles
- Movements
- Proposed Measures
- Attachments
- Certify & Submit

New Applicant

Name	Organization	Role	Phone	
Kurt Brorson	CDER/FDA	Applicant	888-463-6332	Copy Delete



First PPQ ePermits User Workshop

- One-day session, March 10, 2005
 - Primary focus on Pest Permits
 - First product
 - Most interest
- Received input from a diverse set of users including Semenís and STA Laboratories
- Demo of ePermits
- Biotech. Reg. Serv. (BRS) has had two workshops
 - Monsanto
 - Dupont



Plant Pest Permits - To Improve Efficiency and Response Time:

Permits for Widely Prevalent Pathogens (WPP)

- Agreements with APS (American Phytopathological Society) for construction of State-by-State lists of widely prevalent pathogens: fungi, viruses, bacteria and mycoplasmas)
- Creation of New Permitting Process for WPP
 - State pre-approval
 - only for interstate movement of domestic isolates
 - NOT for field study permits



Status of WPP Initiative

WPP lists have been sent to 19 States for review:

Accepted Lists of WPP	Alabama Delaware	Arkansas Georgia	Connecticut	
Accepted most on lists	Colorado Maryland	Florida Oregon	Minnesota North Carolina	Idaho
Rejected entire lists	Hawaii			
No response yet	Alaska Illinois	Arizona Washington	California	Iowa

Virus and Bacteria lists going to remaining 31 States this week



Revision of Plant Pest Permit Regulations (7 CFR Part 330.2)

History

- Proposed Rule Change – 2001
- Plant Protection Act – 2001
- September 11, 2001
- OIG audit of, and alert on permitting

Plan

- Revise and Republish Proposed Rule



United States Department of Agriculture
Animal and Plant Health Inspection Service

Plant Protection and Quarantine



ASTA Requests



Causes of Delay in Processing Permit Applications ?

- Incomplete applications (all types of permits)
- Not including scientific name of seed (e.g., Federal Noxious Weed permits)
- Staffing Issues for Plant Pathogen Permits are now 'resolved'



Which Permit Application Form ?

Disease or Pest Diagnostic Samples	PPQ 526	Pest
Enterable Seeds for Consumption or Propagation	PPQ 587	Plant and Plant Products
Seeds that Require Post Entry Quarantine	PPQ 546	Post Entry
Prohibited Material for Research	PPQ 588	“Departmental”
Seeds of CITES Listed Species	PPQ 621	CITES

All applications available on Web at: www.aphis.usda.gov/ppq/permits



Is a PPQ Permit Needed For ... ?

Lyophilized tissue	Yes, if the material is viable (e.g., viruses or bacteria), or if the intent is to isolate the organisms No, if the material is inviable and noninfective
Extracted DNA/RNA	Viruses: yes, if infective; Bacteria: No; Fungi: No Note: Intent important to decision
Laminated samples	No, if the material is inviable or inaccessible Yes, if material is viable and accessible
Preserved Insects	No, but Customs Declaration (FWS 3-177) may be needed (commercial, yes, personal/private no) BUT... FWS Permit may be needed (See FWS Permit Web site www.fws.gov/permits)



Soil Smudges on Seed Bags, Policy?

- Not a permit issue *per se*
 - Creating a permit condition would be redundant with existing regulations regarding prohibition on soil contaminants
- Port discretion based on perceived risk
 - It takes little soil to present risk of animal or plant disease transmission



Immature Corn Ears

Is this type of material (new technology)
covered by a seed permit

- No
- This is “other plant material”
- To apply for a permit... describe :
 - material to be imported
 - methods used to produce material
 - Intended use and disposition



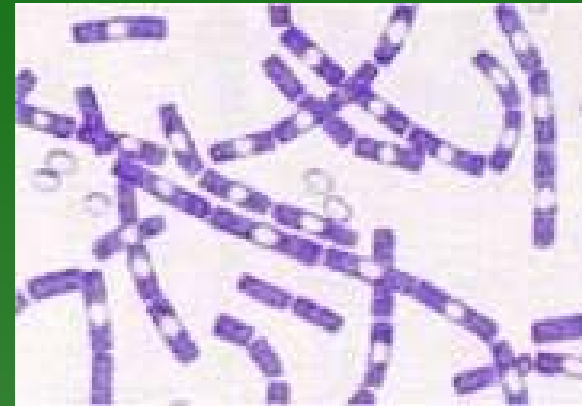
Common Interceptions on Seeds

2000-2005

- 938 host/country/pest combinations
 - Some with multiple interceptions (e.g., 70)
- Most (~60%) on “consumption” seeds
- About 40% on seeds for propagation
- Printout available for review

Permit Conditions

- Standard Conditions on interstate movements being relaxed as appropriate for risk level
- Conditions may reflect requested activities or lab protocols



Public Health Security and Bioterrorism Preparedness & Response Act of 2002

Title II, Subtitle B cited as...

Agricultural Bioterrorism Protection Act of 2002

List of PPQ Select Agents

- *Ralstonia solanacearum*, race 3, biovar 2
- *Candidatus Liberobacter africanus*
- *Candidatus Liberobacter asiaticus*
- *Xanthomonas oryzae* pv. *oryzicola*
- *Xylella fastidiosa* (citrus variegated chlorosis strain)
- *Peronosclerospora philippinensis*
- *Sclerophthora rayssiae* var. *zeae*
- *Synchytrium endobioticum*



Laws & Regulations: Possession and Transfer of Plant Pathogens

Law/Statute	Regulation
Written by U.S. Congress	Written by USDA - as directed by Congress
Plant Protection Act of 2000	7 CFR 330 Plant Pest Permitting
Agricultural Bioterrorism Protection Act of 2002	7 CFR 331 “Select Agent” Program



Permits/SAP Regulatory Requirements

Activity	Permit under PPA/330 ?	Register ABPA/331 ?
Collect samples potentially infected with a Select Agent, send for diagnosis within state	No	No
Collect samples potentially infected with a Select Agent, send interstate for diagnosis	Yes, receiver No, sender	No
Diagnostic lab maintains non-viable spores or extracted genetic material of a Select Agent to use as a positive control	Yes, interstate No, intrastate	No
Diagnostic lab maintains viable Select Agent spores or other material as positive control	Yes, interstate No, intrastate	Yes
Diagnostic lab saves (for whatever purpose) part of a sample later determined to be a Select Agent	Yes, interstate No, intrastate	Yes
Conduct research on a Select Agent (other than pure diagnostics)	Yes, interstate No, intrastate	Yes
Lab (Diagnostic or otherwise) receives <u>known</u> , viable Select Agent from other, permitted lab	Yes, interstate Yes, intrastate	Yes



“Small Lots of Seed for Import without a Phytosanitary Certificate”: Proposed Rule

- Thank you for comment submitted by ASTA
- OMB deemed the Rule Change ‘Significant’
- Draft Final Rule currently in Departmental Review



Plants for Planting: “Revision of Q-37”

- 7 CFR Part 319.37 (Q-37)
 - Principal regulation governing the import of plants for planting
- Other related regs also covered in the revision (all 7 CFR)
 - 319.15 Sugarcane
 - 319.19 Citrus & related genera
 - 319.24 & .41 Corn & related genera
 - 319.55 Rice
 - 319.59 Wheat
 - 319.8 Cotton

Basic Premise of Current Q-37

- Majority of plant taxa are enterable with only a port of entry inspection
- Some plants for planting are further restricted by additional requirements
- Pest risk analysis required only for certain types of importations



Advance Notice of Proposed Rulemaking (ANPR)

- Published Dec 10, 2004
 - “Nursery Stock Regulations”, Docket No. 03-069-1
- Comment period open until April 11, 2005
- View ANPR at:
 - <http://www.aphis.usda.gov/ppd/rad/webrepor/ppq.html>



Revising Q-37: Highlights of the 2004 ANPR

- Programs to reduce risk of entry and establishment
- Establish a new import entry category
- Improve data collection to determine taxa imported, origin, and volume
- Reevaluate taxa currently prohibited
- Incorporate all plants for planting into one regulation



“Revising Q-37”: Stakeholder Meeting/Workshop

- May 25, 2005
- Federal Register Notice to appear soon
- Will register as many as 70 attendees
- Other events are being planned by stakeholder groups



“Departmental” Permits

- For prohibited articles
- Original intention... research, by USDA
- Current usage... various, insufficient oversight
- Strategy for improvement:
 - Phase 1 (now): More appropriate conditions, and more involvement of State Officials
 - Phase 2: Modify name to “Research”, expand beyond USDA
 - Proposed Rule (draft) to modify existing regulations
 - Phase 3: Create new classes of permits (intended use)
 - Example, commercial development



“Q-37 Revision”: Time Frames

Comment Period Closes, ANPR:	April 10, 2005
Analyze ANPR Comments	Begin April, 2005
Stakeholder Meeting/Workshop	May 25, 2005
Proposed Rule, Departmental (Research) Permit	2005
Import of Christmas and Easter Cactus IGM from the Netherlands and Denmark (Proposed Rule)	2005
Proposed Rule, Standards for Including Species on “Exclude Pending PRA List”	Early 2006
Continuing work with NAPPO and globally on development of standards for clean stock programs	2005



Phytosanitary Certification Program

2001 – 2004: approximately 1,200,000
Federal Phytosanitary Certificates (FPCs)
were issued by (Authorized Certification
Officials) ACOs to enable the exportation
of agricultural commodities valued at
approximately \$75 billion



PCIT = Phytosanitary Certificate Issuance and Tracking

- An electronic system
- PPQ is working with an IT contractor to develop the application and data base



PCIT Short-term Goals: On-line processes

- Submission of applications
- Scheduling inspections
- Issuance and printing of paper certificates
- Electronic Fee payment
- Tracking and trace-backs
 - ACOs can track applications from submission to issuance of FPC
- Authenticity of FPCs can be verified if in the system
- Trace-back and auditing functions enhanced



PCIT Benefits

- More timely issuance of Phytosanitary Certificates
- Standardized processes for issuance and recordkeeping
- Improved workload management
- Improved reporting capabilities
- Improved service to U.S. exporters
- Reduced incidence of errors and fraud



PCIT Releases Over a Two Year period

- Release 2.0: Basic program and database (Sept 2005)
- Release 2.5: Payment engine (March 2006)
- Release 3.0: State certificate & Re-export certificates (Dec2006)
- Refinements: Batch printing, Increased data features



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Animal and Plant Health Inspection Service

Plant Protection and Quarantine



END



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Animal and Plant Health Inspection Service

Plant Protection and Quarantine



TITLE

- TEXT



OUTLINE

- PHP Reorganization
- General Permit Issues
- Plant Pest Permits Issues
- Select Agent Issues
- Revision of Q-37 *et al.*
- Phytosanitary Certificate Issuance & Tracking - PCIT
- ASTA Information Requests